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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,991	03/06/2007	Victor A. Raul	71,038-043	5824

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DINSMORE & SHOHL LLP
FIFTH THIRD CENTER, ONE SOUTH MAIN STREET
SUITE 1300
DAYTON, OH 45402-2023

EXAMINER	
PIHONAK, SARAH	

ART UNIT	PAPER NUMBER
1627	

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11/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,991	RAUL ET AL.	
	Examiner	Art Unit	
	SARAH PIHONAK	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *8,13 and 18-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-12,14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/6/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 (national stage application) of PCT/US04/35619, filed on 10/27/2004.

Priority

This application claims priority to Provisional Application No. 60/514709, filed on 10/27/2003.

Response to Restriction Requirement

1. Applicant's election without traverse of the invention of Group I, claims 1-17, in the reply filed on 8/7/2009 is acknowledged. For the species requirement, the following elections were made by the Applicants: for the silicone component, the reaction product of a hydroxyl endblocked polydimethylsiloxane polymer and a hydroxyl functional silicate resin (trimethylsiloxy and hydroxyl endblocked silicate resin); triethanolamine linear alkylate sulfonate for the surfactant; polyvinyl alcohol as the thickening agent; and ketoconazole as the active drug. Claims 1-7, 9-12, 14-17 read on the elected species.

2. Claims 8, 13, and 18-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/7/2009. In the response filed on 8/7/2009, the Applicants stated that claim 18, which is drawn to a method, is incorrectly written as a method claim, and is actually meant to be a dependent claim of claim 1, drawn to a composition. However, it is noted that claim 18 has not been amended to refer to a composition rather than a method. Therefore, this claim is withdrawn.

3. Claims 1-7, 9-12, and 14-17 were examined.

4. Claims 1-7, 9-12, and 14-17 are rejected.

Claim Rejections-35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-7, 9-12, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosal, US Patent No. 6,545,086, in view of Gray et. al., US Patent No. 6,040,307, and further in view of Ulrich, US Patent No. 6,365,146.

The claims are drawn to a controlled-release composition for topical application comprising an oil-in-water emulsion of a silicone component formed from the reaction of a hydroxyl endblocked polydimethylsiloxane polymer and a hydroxyl functional silicate resin (trimethylsiloxy and hydroxyl endblocked silicate resin); the surfactant triethanolamine linear alkylate sulfonate; an additional silicone-based surfactant as a dispersing agent, polyvinyl alcohol as a thickening agent; and the drug ketoconazole. The claims are also drawn to the silicone component as a pressure sensitive adhesive, and to the active drug being present in a liquid, viscous, powder, or crystalline form.

Kosal teaches an oil-in-water emulsion composition comprised of a pressure sensitive adhesive, a surfactant, and a thickening agent for medical and personal care utility (Abstract; column 1, lines 16-24). The pressure sensitive adhesive is taught as being comprised of a crosslinking reaction between a hydroxyl terminated polydiorganosiloxane such as hydroxy terminated polydimethylsiloxane, and a silanol containing silicone resin (column 2, lines 30-60). It is taught that the silanol containing silicone resin has hydroxyl end groups, as well as trimethyl end groups (column 2, lines 45-60). It is taught that polyvinyl alcohol is used as a thickening agent (column 5, lines 4-13), and that the triethanolamine linear alkylate sulfonate surfactant, known commercially as Bio-Soft N-300 is present in the composition as a surfactant (column 6, Example 1, lines 36-39). Silicone based surfactants, such as those comprised of

siloxane polyalkylene copolymers, are taught, as well as combinations of surfactants (column 3, line 66-column 4, line 18). Kosal teaches that the emulsion composition comprised of the pressure sensitive adhesive, polyvinyl alcohol, and triethanolamine linear sulfonate is used in medical applications, such as transdermal drug delivery, and to maintain an active drug, such as a fungicide, to the surface of the skin (column 5, lines 14-30). While Kosal does not explicitly teach that the drug delivery to the skin is in the form of sustained or controlled release, transdermal drug delivery is taught. It is well known in the art that transdermal drug delivery is used to provide a controlled release of the desired active agent to the skin of the subject or patient. While Kosal does not explicitly teach that the silicone component and surfactant comprise a homogeneous oil phase, the surfactant, triethanolamine dodecylbenzene sulfonate and the silicone component are mixed together, followed by addition of water to form an oil-in-water emulsion (column 6, lines 30-48); thus, the combination of the silicone component and surfactant comprises the oil phase, which, without evidence to the contrary, would have been expected to be homogeneous.

While Kosal teaches a composition comprised of a pressure sensitive adhesive (formed by reaction of a hydroxyl endblocked polydimethylsiloxane polymer and a hydroxyl functional silicate resin (trimethylsiloxy and hydroxyl terminated silicate resin), polyvinyl alcohol, and the triethanolamine dodecylbenzene sulfonate surfactant, or Bio-Soft N-300 is effective as a transdermal drug delivery system or to hold a fungicide to the skin of a patient, it is not explicitly taught that the active drug contained in the system is ketoconazole.

Gray et. al. teaches that ketoconazole is a fungicide useful for fungal infections of the skin, as well as systemic infections (Abstract; column 1, lines 15-21). Gray et. al. teaches that ketoconazole can be administered by a variety of routes, including topically (column 6, lines 18-25; lines 61-63). It is also taught that ketoconazole can be administered in a controlled release or controlled delivery manner (column 6, lines 64-67), and administered topically as a solid, semi-solid, solution, powder, or a viscous form (column 7, lines 32-45).

It would have been prima facie obvious for one of ordinary skill in the art, at the time of the invention, to prepare a composition comprised of the pressure sensitive adhesive, surfactant, thickener, and emulsion taught by Kosal and the active agent ketoconazole because Kosal teaches that the pressure sensitive adhesive comprised oil-in-water emulsion is effective for transdermal drug delivery, and for maintaining fungicidal active agents on the surface of skin. As ketoconazole is taught by Gray et. al. as a fungicide for treating local and systemic infections, and can be administered topically and in controlled release formulations, one of ordinary skill in the art would have expected success in utilizing the composition taught by Kosal to deliver ketoconazole in a controlled release manner topically, for drug delivery.

While Kosal does not explicitly teach that the surfactants encapsulate the active agent, Ulrich teaches that surfactants are commonly used for drug delivery, as the micelles formed from the surfactant are able to solubilize hydrophobic drugs, within a hydrophilic outer shell (column 1, lines 45-51). Therefore, as it is taught that surfactants are effective for solubilizing hydrophobic drugs, and form a hydrophilic outer shell, it

would have been obvious that the surfactants taught by Kosal in effect encapsulate the active agent, ketoconazole.

Information Disclosure Statement

9. The information disclosure statement (IDS) submitted on 3/6/2007 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 8:00 AM - 6:30 PM EST, with Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.P.

/Shengjun Wang/
Primary Examiner, Art Unit 1627